Aram V. Desteian
Attorney

612.746.1088
612.746.1288 *fax*

adesteian@bassford.com

BASSFORD REMELE
A Professional Association
33 South Sixth Street, Suite 3800
Minneapolis, MN 55402-3707

612.333.3000
612.333.8829 *fax*

www.bassford.com

July 26, 2016

VIA U.S. MAIL

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

Re: *FOIA Request – Syngenta AG, Syngenta Crop Protection AG, Syngenta Corp., Syngenta Crop Protection, LLC, Syngenta Biotechnology, Inc., Syngenta Seeds, LLC, and Syngenta Seeds, Inc.*

Dear FOIA Disclosure Officer:

I am writing to request documents and information pursuant to FOIA involving the regulatory approval for several Syngenta corn seed biotechnology traits and products for which Syngenta applied for and received EPA approval.

This law firm has been appointed as a Co-Lead of the Plaintiffs' Executive Committee overseeing the prosecution of nearly 50,000 individual plaintiff claims against the Syngenta companies over the premature release of two of their genetically modified corn seeds, which were previously granted EPA approval. The litigation is pending in the County of Hennepin, District of Minnesota court before the Honorable Judge Sipkins, Case No. 27-cv-15-3785. I believe this request falls under fee category 4. We will pay fees up to $200. If the fee will be more, please contact me.

The timeframe I am requesting documents for is from 2007 to the present. I am requesting the following documents for corn varieties that contain MIR162, BT corn traits, MIR604, Event 5307, Viptera, Duracade, individually or any combination of any one or more of these traits or brands:

1. All registrations filed by Syngenta AG, Syngenta Crop Protection AG, Syngenta Corporation, Syngenta Crop Protection, LLC, Syngenta Biotechnology, Inc., Syngenta Seeds, LLC, and Syngenta Seeds, Inc. (collectively hereafter "Syngenta");

2. All compliance documents, reports, or memorandum required filed by Syngenta or third parties on Syngenta's behalf;

3. All reports of quantities or locations of plantings including annual quantities sold and acres planted by state and county submitted by Syngenta or a third party on Syngenta's behalf;

4. Reports and information on "channeling," separation, or segregation of these corn varieties submitted by Syngenta or a third party on Syngenta's behalf;

5. Reports, communications, and documents regarding compliance with grower agreement or stewardship obligations submitted by Syngenta or a third party on Syngenta's behalf;

6. All stewardship documents, including copies of grower agreements or stewardship agreements filed with the EPA;

7. Any communications regarding China, the European Union, Japan, or other countries rejecting U.S. corn containing any of the identified traits;

8. All Insect Resistance Management reports;

9. All Compliance Assurance Programs;

10. All documents concerning education programs, multimedia programs, face-to-face meetings, mailings of written materials, copies of the mailed written materials, copies of seed bag and seed bag tags, electronic communications to growers, copies of the educational material Syngenta used on the internet, radio, television, and/or television commercials;

11. A copy of the written communication Syngenta was required to send "annually to each Btll X MIR162 X MIR 604 corn user separate from the grower technical guide" per the EPA requirement imposed on Syngenta in 2009 related to Agisure Viptera 3111 (*See* Ex. A, at p. 6);

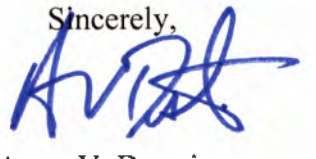
12. A copy of the documents Syngenta submitted to the EPA to show compliance with the EPA's requirement that Syngenta annually "shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high." (*See* Ex. A, at p. 6);

13. A copy of the annual report Syngenta submitted to the EPA to show compliance with the EPA's requirement that "[a]nnually, Syngenta must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Syngenta must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC)." (*See* Ex. A, at p. 6); and

14. All documents submitted by Syngenta or a third party acting on Syngenta's behalf in support of registration of each identified variety or trait.

I would be glad to discuss this request with you to provide any information that will aid your search or avoid undue time and expense. Please contact me with any questions or concerns.

Sincerely,



Aram V. Desteian

AVD:mmb
Encl.
1556866.docx

EXHIBIT A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Registration Number:	Date of Issuance:
67979-13	DEC 22 2011
Term of Issuance:	Conditional, Time Limited

NOTICE OF PESTICIDE:

X Registration
_____ Reregistration
(under FIFRA, as amended)

Name of Pesticide Product:
Bt11 x MIR162 x MIR604 corn

Name and Address of Registrant (include ZIP Code):

Syngenta Seeds, Inc. – Field Crops – NAFTA
3054 East Cornwallis Road
P.O. Box 12257
Research Triangle Park, NC 27709-2257

Note: Changes in labeling, differing in substance from that accepted in connection with this registration, must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act). Registration is in no way to be construed as an endorsement or recommendation of this product by the Environmental Protection Agency (EPA or the Agency). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you comply with the following terms and conditions:

1) The subject registration will automatically expire at midnight on December 31, 2013.

2) The subject registration will be limited to Cry1Ab [*Bacillus thuringiensis* Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (OECD Unique Identifier: SYN-BTØ11-1)] x Vip3Aa20 [*Bacillus thuringiensis* Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (OECD Unique Identifier: SYN-IR162-4)] x mCry3A [*Bacillus thuringiensis* mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn event MIR604 (OECD Unique Identifier: SYN-IR6Ø4-5)] for use in field corn.

Signature of Approving Official:	Date:
Keith A. Matthews, Director Biopesticides and Pollution Prevention Division	22 December 2011

CONCURRENCES

EPA Form 8570-6

SYMBOL	7511P	7511P						
SURNAME	KAUSCH	MATTHEWS						
DATE	12/22/2011	12/22/11						

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* **OFFICIAL FILE COPY**

Bt11 x MIR162 x MIR604 corn
EPA Reg. No. 67979-13

3) Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.

4) Submit/cite all data and/or information, which are required to support individual plant-incorporated protectants in YieldGard® Insect Resistant Corn, MIR162 maize, and Agrisure® RW Rootworm-Protected Corn within the time frames required by the terms and/or conditions of EPA Registration Numbers 67979-1, 67979-14, and 67979-5, respectively. These data and/or information must be determined by EPA to be acceptable.

5) This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

6) You must submit the following data and/or information in the time frames listed:

Study Type	Required Data/Information	Due Date
Insect Resistance Management – Grower Agreement	A copy of the grower agreement, associated stewardship documents, and written description of a system, which assure that growers will sign grower agreements and persons purchasing Bt11 x MIR162 x MIR604 corn will annually affirm that they are contractually bound to comply with the requirements of the insect resistance management (IRM) program, must be submitted.	March 30, 2012
Insect Resistance Management – Compliance	A revised compliance assurance program (CAP) to address the items in section 7(c) (paragraphs 16–22) of this registration notice.	March 30, 2012

7) You must commit to do the following IRM Program, consisting of the following elements:

- Requirements relating to creation of a refuge for the Cry1Ab, Vip3Aa20, and mCry3A components that meets the requirements of the individual traits. The refuge for these traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1Ab and Vip3Aa20 components, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the mCry3A component.

- Requirements for Syngenta Seeds, Inc. – Field Crops – NAFTA (Syngenta) to prepare and require Bt11 x MIR162 x MIR604 corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.

- Requirements for Syngenta to develop, implement, and report to EPA on programs to educate growers about IRM requirements.

- Requirements for Syngenta to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.

- Requirements for Syngenta to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1Ab, Vip3Aa20, and/or mCry3A proteins in the target insects.

- Requirements for Syngenta to develop, and if triggered, to implement a remedial action plan that would contain measures Syngenta would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.

- Requirements for Syngenta, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will made available to EPA upon request), IRM grower agreement results, and the compliance assurance program, including the education program.

- Requirements for Syngenta, on or before August 31st of each year, to submit reports on resistance monitoring.

a. Refuge Requirements for Bt11 x MIR162 x MIR604 Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States total of 250,000 acres per plant-incorporated protectant active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance will be provided by Syngenta to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

For Bt11 x MIR162 x MIR604 corn, two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn borers or corn rootworms. The common refuge area must represent at least 20% of the grower's corn

reaches an economic threshold for damage; however, if corn rootworm adults are present at the time of foliar applications, then the Bt11 x MIR162 x MIR604 corn field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Pests other than adult corn rootworms can be treated with an appropriate pest-labeled insecticide on the corn rootworm refuge acres without treating the Bt11 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the Bt11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the corn rootworm refuge.

b. Grower Agreements for Bt11 x MIR162 x MIR604 Corn

1) Persons purchasing Bt11 x MIR162 x MIR604 corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Syngenta must continue to implement a system, which is reasonably likely to assure that persons purchasing Bt11 x MIR162 x MIR604 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Syngenta must continue to use its current grower agreement for Bt11 x MIR162 x MIR604 corn. If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.

5) Syngenta must continue to implement an approved system, which is reasonably likely to assure that persons purchasing Bt11 x MIR162 x MIR604 corn sign grower agreement(s).

6) Syngenta shall maintain records of all Bt11 x MIR162 x MIR604 corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

7) Annually, Syngenta shall provide EPA with a report showing the number of units of Bt11 x MIR162 x MIR604 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the 12-month period covering the prior August through July.

17) Syngenta will enhance the refuge education program throughout the seed delivery channel:

i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.

ii. Include the refuge size requirement on all Bt11 x MIR162 x MIR604 corn seed bags or bag tags. The Bt11 x MIR162 x MIR604 corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three (3) growing seasons. Revised Bt11 x MIR162 x MIR604 corn labels must be submitted by March 30, 2012, 50% implementation on the Bt11 x MIR162 x MIR604 corn bags or bag tags must occur by the 2013 growing season, and full implementation must occur by the 2014 growing season.

18) Syngenta will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.

ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Bt11 x MIR162 x MIR604 corn is used.

19) Syngenta will use its available Bt11 x MIR162 x MIR604 corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Bt11 x MIR162 x MIR604 corn but may have purchased little or no refuge seed from Syngenta, licensees, or affiliated companies.

20) Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments, of those growers found out of compliance in a first-time assessment.

iv. Syngenta must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season, with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to mCry3A. As part of the effort, Syngenta may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm.

v. Syngenta must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage). The revised guidelines must take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for mCry3A.

vi. Syngenta must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.

vii. Syngenta must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.

viii. The following program summary describes, in order or events, the steps that must be taken to implement a remedial action plan if resistance to corn rootworm is confirmed (this general process has been implemented for other lepidopteran and corn rootworm *Bt* corn products).

1. *Definition of Suspected Resistance*. Resistance will be suspected if investigations of unexpected damage reports show that:

    - implicated maize plant roots were expressing the mCry3A protein at the expected level;
    - alternative causes of damage or lodging, such as nontarget pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out;
    - the level of damage exceeds guidelines for expected damage.

If resistance is suspected, Syngenta will instruct affected growers to use alternate pest control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.

2. *Confirmation of Resistance.* Resistance will be confirmed if all of the following criteria are met by progeny from the target pest species sampled from the area of suspected resistance:

    - the proportion of larvae that can feed and survive on mCry3A roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
    - the LC_{50} of the test population exceeds the upper limit of the 95% confidence interval for the LC_{50} of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;
    - the ability to survive is heritable;
    - mCry3A plant assays determine that damage caused by surviving insects would exceed economic thresholds; and
    - the identified frequency of field resistance could lead to widespread product failure if subsequent collections in the affected field area(s) demonstrated similar bioassay results.

3. *Response to Confirmed Resistance.* When resistance is confirmed, the following steps will be taken:

    - EPA will receive notification within thirty (30) days of resistance confirmation;
    - affected customers and extension agents will be notified about confirmed resistance;
    - affected customers and extension agents will be encouraged to employ alternative corn rootworm control measures;

recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of Bt11 x MIR162 x MIR604 corn. EPA shall be consulted prior to the implementation of such modifications.

Syngenta will report to EPA, on or before August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1Ab and/or Vip3Aa20 proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to EPA annually on or before August 31st. The investigative steps will include the following:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to Bt11 x MIR162 x MIR604 corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:

    - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);

    - estimating the resistance allele frequency in the original population;

    - determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;

- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with EPA to develop and implement a case-specific resistance management action plan.

Investigation of Reports of Unexpected Levels of Damage by the Target Pests

Syngenta will follow up on grower, extension specialist, or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Syngenta will implement the actions described below, based on the following definitions of ***suspected resistance*** and ***confirmed resistance***.

Suspected Resistance

EPA defines ***suspected resistance*** to mean field reports of unexpected levels of insect-feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

EPA does not interpret ***suspected resistance*** to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to Bt11 x MIR162 x MIR604 corn in commercial production fields before responsive measures are undertaken.

If resistance is ***suspected***, Syngenta will instruct growers to do the following:

- Use alternative control measures in Bt11 x MIR162 x MIR604 corn fields in the affected region to control the target pest during the immediate growing season.

- Destroy Bt11 x MIR162 x MIR604 corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residues, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed Resistance

EPA defines ***confirmed resistance*** to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all of the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).

- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.

- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

<u>Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field</u>

When field resistance is ***confirmed*** (as defined above), the following steps will he taken by Syngenta:

- EPA will receive notification within thirty (30) days of resistance confirmation;

- Affected customers and extension agents will be notified about confirmed resistance within thirty (30) days;

- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;

- Syngenta will develop a case-specific resistance management action plan within ninety (90) days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators, and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and

- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA, on or before August 31st of each year, for the duration of the registration.

e. Annual Reporting Requirements for Bt11 x MIR162 x MIR604 Corn

1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.

Bt11 x MIR162 x MIR604 corn
EPA Reg. No. 67979-13

2) Grower Agreement Results: number of units of Bt11 x MIR162 x MIR604 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.

3) Grower Education: substantive changes to the education program completed during the previous year, on or before January 31st of each year.

4) Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.

5) Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31st of each year.

6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of this product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,

Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

Bt11 x MIR162 x MIR604 Corn

[Alternate brand name: *Agrisure™ 3100*]

OECD Unique Identifier: SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5

Plant-incorporated protectant:
Cry1Ab, Vip3Aa20 and mCry3A proteins for control of corn borers, other lepidopteran pests and corn rootworms

This product is effective in controlling corn leaf, stalk, and ear damage caused by certain lepidopteran pests and root feeding damage caused by corn rootworms.

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1)..... ≤ 0.0017%*

Bacillus thuringiensis Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)..... ≤ 0.0088%*

Bacillus thuringiensis mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn event MIR604 (SYN-IR6Ø4-5)..... ≤0.0021%*

Other Ingredients:

A marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1)..... ≤ 0.0001%*

A marker protein and the genetic material necessary for its production (via elements of vectors pNOV1300 and pZM26) in corn events MIR162 and MIR604 (SYN-IR162-4 and SYN-IR6Ø4-5)..... ≤ 0.00095%*

*Percent in whole plants on a dry weight basis

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-13
EPA Establishment No. 66736-NC-01

Syngenta Seeds, Inc. -Field Crops-NAFTA
3054 East Cornwallis Rd
Research Triangle Park, NC 27709

™ Agrisure is a trademark of a Syngenta Group company

DIRECTIONS FOR USE

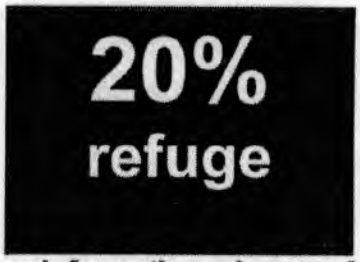
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

The subject registration will automatically expire at midnight on December 31, 2013.

This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

All maize seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds, Inc. or its distributors must be accompanied by informational material (e.g., a bag tag) indicating the registration number (67979-13) and the active ingredients, and stipulating that growers read the Grower Guide (or equivalent guidance) prior to planting the seed.

Important grower information.
Please read before planting.



For more information, please refer to the Syngenta Stewardship guide

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab, Vip3Aa20 and mCry3A, for control or suppression of the following lepidopteran and coleopteran insects:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
Beet armyworm (*Spodoptera exigua*)
Black cutworm (*Agrotis ipsilon*)
Western bean cutworm (*Striacosta albicosta*)
Sugarcane borer (*Diatraea saccharalis*)
Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)

Mexican corn rootworm (*Diabrotica virgifera zeae*)
Common stalk borer (*Papaipema nebris*)
Dingy Cutworm (*Feltia jaculifera*)

Insect Resistance Management

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

Refuge Requirements for Bt11 x MIR162 x MIR604 Corn

The following information regarding commercial production of Bt11 x MIR162 x MIR604 corn must be included in the Grower Guide (or equivalent).

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

Two options for deployment of the refuge are available to growers.

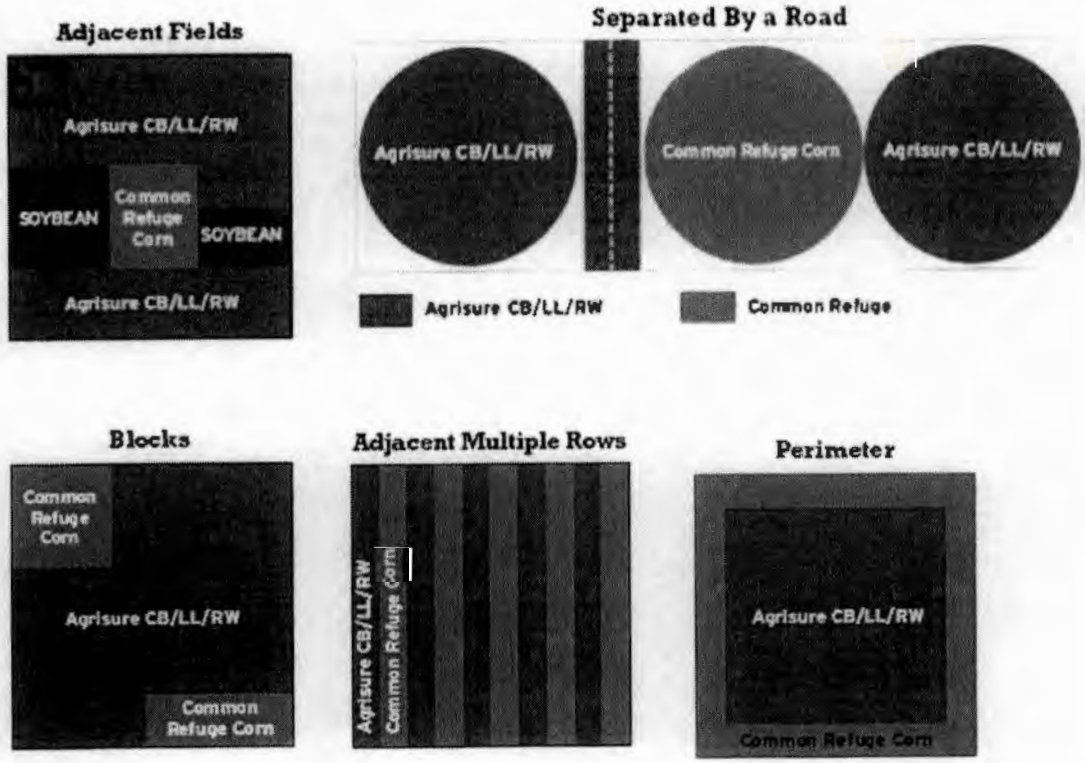
The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR162 x MIR604 corn field. Refuge planting options include separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control or a non-Bt foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and corn rootworm refuge acres), and must be planted as an adjacent block, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. If the corn rootworm refuge is planted on rotated ground, then Bt11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the corn rootworm refuge is planted in continuous corn, the Bt11 x MIR162 x MIR604 corn field may be planted on either continuous or rotated land. More generally, the corn rootworm refuge should utilize comparable agronomic practices as the Bt11 x MIR162 x MIR604 corn acres. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control corn rootworm larvae and other soil pests. The corn rootworm refuge can also be treated with a non-Bt foliar insecticide for control of late season pests, if pest pressure reaches an economic threshold for damage; however, if corn rootworm adults are present at the time of foliar applications, then the Bt11 x MIR162 x MIR604 corn field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Pests other than adult corn rootworms can be treated on the corn rootworm refuge acres without treating the Bt11 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the Bt11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the corn rootworm refuge.

The following is a schematic of separate refuge deployment options:

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn rootworms or corn borers. The common refuge area must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and common refuge acres). It must be planted as a block adjacent to the Bt11 x MIR162 x MIR604 corn field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. If the common refuge is planted on rotated ground, then Bt11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the Bt11 x MIR162 x MIR604 corn field may be planted on either continuous or rotated land. The common refuge can be treated with a soil-applied or seed-applied insecticide to control corn rootworm larvae and other soil pests. The common refuge can also be treated with a non-Bt foliar insecticide for control of late season pests, if pest pressure reaches an economic threshold for damage; however, if corn rootworm adults are present at the time of foliar applications, then the Bt11 x MIR162 x MIR604 corn field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Pests other than adult corn rootworms can be treated with an appropriate pest-labeled insecticide on the common refuge acres without treating the Bt11 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Bt11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the common refuge.

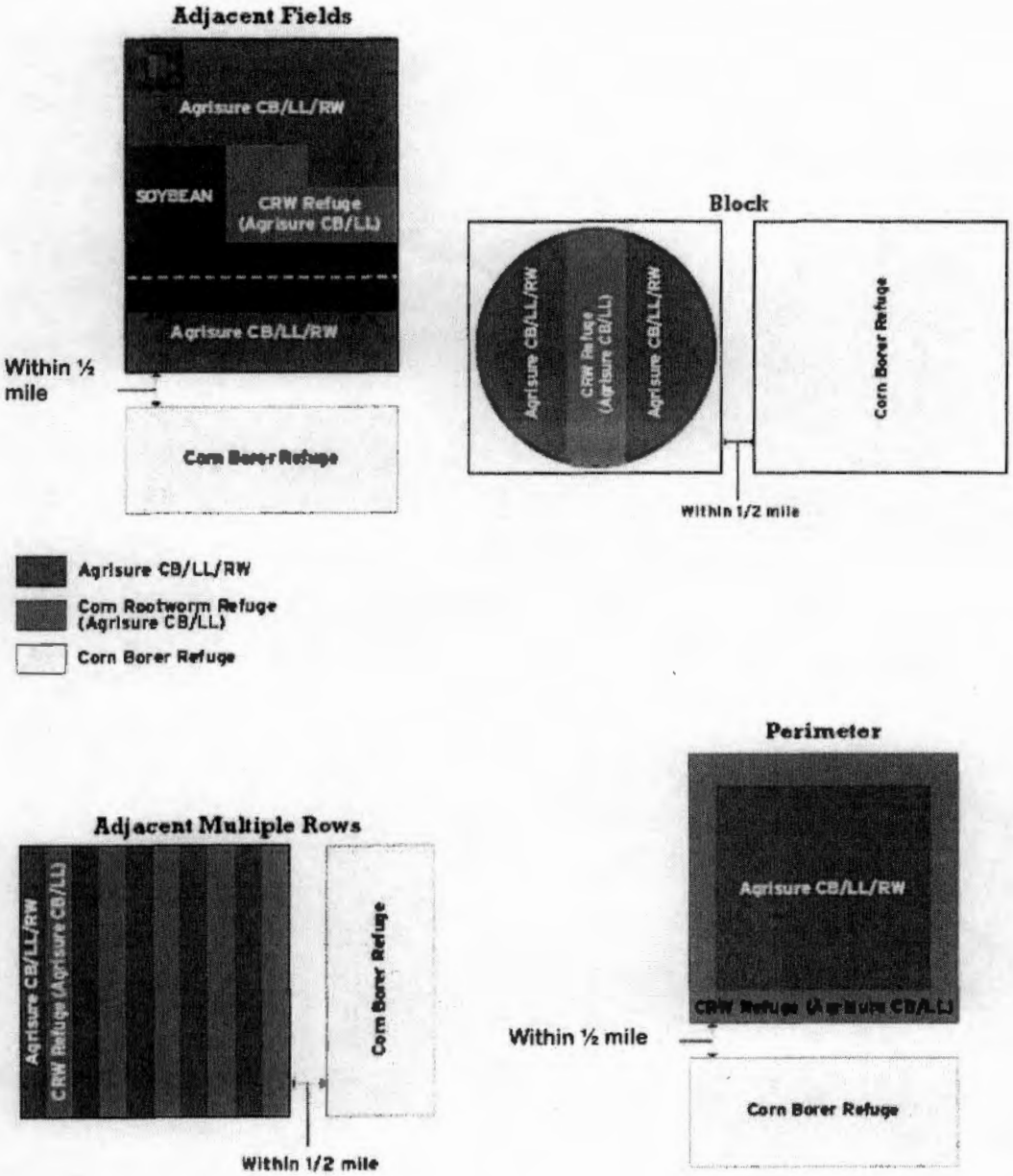
The following is a schematic of common refuge deployment options:



The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR162 x MIR604 corn field. Refuge planting options include separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control or a non-Bt foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and corn rootworm refuge acres), and must be planted as an adjacent block, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. If the corn rootworm refuge is planted on rotated ground, then Bt11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the corn rootworm refuge is planted in continuous corn, the Bt11 x MIR162 x MIR604 corn field may be planted on either continuous or rotated land. More generally, the corn rootworm refuge should utilize comparable agronomic practices as the Bt11 x MIR162 x MIR604 corn acres. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control corn rootworm larvae and other soil pests. The corn rootworm refuge can also be treated with a non-Bt foliar insecticide for control of late season pests, if pest pressure reaches an economic threshold for damage; however, if corn rootworm adults are present at the time of foliar applications, then the Bt11 x MIR162 x MIR604 corn field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Pests other than adult corn rootworms can be treated on the corn rootworm refuge acres without treating the Bt11 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the Bt11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the corn rootworm refuge.

The following is a schematic of separate refuge deployment options:


Adjacent Fields
Agrisure CB/LL/RW
SOYBEAN
CRW Refuge (Agrisure CB/LL)
Agrisure CB/LL/RW
Within ½ mile
Corn Borer Refuge
Block
Agrisure CB/LL/RW
CRW Refuge (Agrisure CB/LL)
Agrisure CB/LL/RW
Corn Borer Refuge
Within 1/2 mile
Agrisure CB/LL/RW
Corn Rootworm Refuge (Agrisure CB/LL)
Corn Borer Refuge
Adjacent Multiple Rows
Agrisure CB/LL/RW
CRW Refuge (Agrisure CB/LL)
Corn Borer Refuge
Within 1/2 mile
Perimeter
Agrisure CB/LL/RW
Within ½ mile
Corn Borer Refuge